K011797

JUL - 3 2001

2 Summary and Certification

2.1 *Premarket Notification 510(k) Summary*

SUBSTANCIAL EQUIVALENCE:
Identification of predicate devices, models, and manufacturers:

Predicate electrode device:	CardioDynamics BioZtect Sensor within BioZ.com System
Model:	Part # BZ-4550
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K001100
Reason for Submission:	Modifications to electrode shape, material, gel, thickness, and snap size

Predicate cable device:	CardioDynamics BioZtect Cable within BioZ.com System
Model:	Part # BZ-4540
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K001100
Reason for Submission:	Modifications to leadwire connector size, change style of module connector, addition of series inductors for each conductor, and addition of identification integrated circuit

GEMS received acceptance of the 510(k) Notification Submission K010164 on 5/24/01 for the GE Medical Systems Solar ICG Module with standard cable and standard sensors.

The purpose of this submission is to file for the replacement accessories, the BioZtect Sensor and BioZtect Cable. These accessories, when used with the ICG Module, comprise a device that is substantially equivalent to the predicate device currently marketed by CardioDynamics International Corporation. The justification for this substantial equivalence determination is presented below.

The ICG Module with accessories BioZtect Sensor and BioZtect Cable are substantially equivalent to the predicate BioZ.com System in terms of design, intended use and principle of operation, having minimally modified these accessories. Both systems are for use in the hospital, outpatient and clinical settings. The intended use is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG). Monitoring is accomplished by attaching 8 electrodes to the patient (two on each side of the neck and thorax), injecting a minimal current through the upper electrodes, and reading the returning voltage waveform from the inner electrodes.

The ICG Module utilizes CardioDynamics' proprietary DSP electronic circuitry and software, incorporating formulas and algorithms to calculate the various hemodynamic parameters. The user inputs patient parameters into the ICG Module, including patient gender, body frame size, height, weight, age and blood pressure. The module then utilizes these parameters and measures the ICG signals to determine the hemodynamic properties of that particular patient.

Both the predicate BioZ.com System and the ICG Module with accessories BioZtect Sensor and BioZtect Cable utilize a computer-based system. Each system contains the following:

1. BioZ or ICG Module
    a) CardioDynamics' proprietary DSP hardware and Patient Interface Circuitry
    b) CardioDynamics proprietary DSP firmware and user software
2. BioZtect Sensors
3. BioZtect Patient Cable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2001

Mr. Dennis G. Hepp
Chief Technology Officer
CardioDynamics International Corporation
6175 Nancy Ridge Drive, #300
San Diego, CA 92121

Re: K011797
Trade Name: BioZtect Sensor and BioZtect Cable
Regulation Number: 870.2770
Regulatory Class: II (two)
Product Code: 74 DSB
Dated: June 7, 2001
Received: June 8, 2001

Dear Mr. Hepp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2 *Indications for Use:*

The BioZtect Sensor and BioZtect Cable are used with the GE Medical Systems Solar ICG (Impedance Cardiography) Module (K010164) and are intended to monitor and display a patient's hemodynamic parameters. The following are parameters that are available, to be used as needed by the ICG Module:

Acceleration Index, Cardiac Output, Cardiac Index, ECG, End Diastolic Volume, End Diastolic Index, Heart Rate, Index of Contractility, Indexed Systemic Vascular Resistance, Left Cardiac Work, Indexed Left Cardiac Work, Left Ventricular Ejection Time, Pre-Ejection Period, Stroke Volume, Stroke Index, Systolic Time Ratio, Systemic Vascular Resistance, Thoracic Fluid Content, Respiration Rate, Velocity Index

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over-The-Counter Use** _____
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011797